



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

**TECHNICAL REVIEW BRANCH  
SIMILARITY DETERMINATION**

23/APR/2013

MEMORANDUM

Subject:      Name of Pesticide Product:    Scholar EZ  
                 EPA Reg. No. /File Symbol:   100-RLNL  
                 DP Barcode:                      D410482  
                 Decision No:                      475789  
                 Action Code:                        R320  
                 PC Code:                            071503 (fludioxonil)

From:          Eugenia McAndrew, Biologist  
                 Technical Review Branch  
                 Registration Division (7505P)

To:             Erin Malone, RM Team 20  
                 Fungicide Branch  
                 Registration Division (7505P)

Applicant:    Syngenta Crop Protection, LLC  
                 P.O. Box 18300  
                 410 Swing Road  
                 Greensboro, NC 27419-8300

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Fludioxonil	98.0
<u>Other Ingredients:</u>	<u>2.0</u>
Total:	100.0%

**ACTION REQUESTED:** The Risk Manager requests: “I have received an application for a proposed fludioxonil end use product that would only be used as a fogger for pome fruit. To do this, the registrant is essentially just taking the technical and adding it to a fogging machine.”

**BACKGROUND:** Syngenta Crop Protection, LLC has applied for registration of Scholar EZ, EPA File Symbol 100-RLNL, claiming to be substantially similar in composition to Fludioxonil Technical, EPA Reg. 100-759. The proposed product is a protective end use product used to aid in the control of post-harvest diseases in storage facilities. The cited product is a technical product for formulation into end-use fungicides. Both products contain 98% fludioxonil. The submission includes a basic CSF dated March 1, 2013, a label, data matrix and company letter.

The registrant is using the selective method of data support to satisfy the acute toxicity data requirements. The data matrix cites acute toxicity studies with MRIDs 431241-05, -06, -07, -08 and 430800-19 and -24. A search of the OPP electronic databases shows that these studies, which were conducted on technical grade material, were submitted to support the registration of the cited product, 100-759. They were reviewed and classified as acceptable by the Health Effects Division in 1995 (McMahon; D2063332, D206333, D213212 and D211072; 03/Aug/1995).

The label submitted for the proposed product indicates that it will be used on pome fruit. The label for the cited product includes a use for pome fruit.

#### **RECOMMENDATIONS:**

1. TRB compared the basic CSFs of the proposed product, 100-RLNL, and the cited product, 100-759, and determined that the two products are substantially similar in composition. The cited acute toxicity data may be used to support the registration of 100-RLNL.

2. The acute toxicity profile for the proposed product, Scholar EZ, EPA File Symbol 100-RLNL, is as follows:

acute oral toxicity	IV	(LD <sub>50</sub> > 5000 mg/kg)	cited	MRID 43124105
acute dermal toxicity	III	(LD <sub>50</sub> > 2000 mg/kg)	cited	MRID 43124106
acute inhalation toxicity	IV	(LC <sub>50</sub> > 2.636 mg/L)	cited	MRID 43080019
primary eye irritation	III		cited	MRID 43124107
primary skin irritation	IV		cited	MRID 43124108
dermal sensitization	negative		cited	MRID 43080024

3. This memorandum pertains only to the decision concerning whether the subject product is similar to the cited product from an acute toxicological view point. For the purposes of this action, TRB has made no further determination of the adequacy of the toxicological data base or the precautionary label of the cited product.

4. The proposed basic CSF submitted for 100-RLNL was reviewed and accepted by the TRB Product Chemistry Team (Gairola; D410481; EPA File Symbol 100-RLNL; 17/APR/2013).

**LABELING:** Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

**PRODUCT ID #:** 000100-01505

**PRODUCT NAME:** Scholar EZ

**PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** CAUTION

**Hazards to Humans and Domestic Animals:**

Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. [Wear protective eyewear.]\*

\*[Protective eyewear may be specified, if appropriate.]

**First Aid:**

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.